871

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 1448-RNA
BURSAN 11-M4 (Modified Barium Metaborate)

FROM: Lucy D. Markarian 6/26/90
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C)

E 6/27/90

TO: Susan Lewis (PM 21)
Fungicide - Herbicide
Registration Division (H75-05C)

APPLICANT: Buckman Laboratories, Inc.
1256 North McLean Blvd.
Memphis, TN 38108

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Barium metaborate as $BaB_2O_4 \cdot H_2O$	50
Inert Ingredient(s):	50
Total	100.0%

135

INERT INGREDIENT INFORMATION IS NOT INCLUDED

BACKGROUND: Buckman Laboratories Inc. has submitted inhalation data as support for the registration of Bursan 11-M4 under EPA registration Symbol 1448-RNA. The data is gathered using Bursan 11-M1, registered under EPA file symbol 1448-17 and is a manufacturing product composed of 90% Barium Metaborate. Bursan 11-M4 is 50% Bursan 11-M1 and 50% inerts. That includes [redacted] and is an end use product used as paint additive.

It is requested that the adequacy of this test as support for the end product be decided.

Recommendation

Code of Federal Regulations (40CFR ch I #158.340) requires that all end products to be registered need to have support in inhalation toxicity. Where as the active ingredient is a registered manufacturing product and the test presented supports that product, Bursan 11-M4 doesn't have the same percentage of active ingredient, barium metaborate, and has an inert that may also cause toxicity.

Therefore it is concluded that while the test is very much acceptable it doesn't support the end product. The applicant must submit inhalation data in support of their product Bursan 11-M4.

BEST AVAILABLE COPY

-1-/33

CC8872

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3)

Product Manager: (21)
Reviewer: Lucy J. Markarian
MRID No.: 137048
Report Date: 6/26/90
Testing Laboratory: Hazleton Labs. of America Inc. Va
Report No. 39-178
Author(s): Tracey Zeotis
Species: Rat, Sprague Dawley
Sex : 15 ♂ +15 ♀
Weight: Mean group weights 221-241 g
Source: Charles River Breeding Laboratories, Kingston, N.Y.
Test Material: Bursan II-M1
Quality Assurance (40 CFR §160.12): included

Summary:

1. LC_{50} (mg/kg): Males = _____; Females = _____; Combined = _____
2. The estimated LC_{50} is Greater than 3.54 mg/L
3. Mean Concentration: _____
4. Tox. Category : III . Classification: Core Guidelines

Procedure (Deviations From §81-2): Exposure was in 100 L glass and stainless steel chambers for the Two test groups and in a plexiglass chamber for the control group. The Test material were introduced into the chamber using two weight dust feeds generating into the

Results:

Reported Mortality

Exposure Concentration (mg/L)	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
0	0/5	0/5	0/10
2.98	1/5	0/5	1/10
3.54	0/5	1/5	1/10

Symptomology & Gross Necropsy Findings:

Tangential input dust at the Turret top of the chamber. Air flow was at 16.7 L/min for group 3. For group 2 the generator air flow was at 10.0 L/min and 6.7 L Accessory flow. Exposure at all levels was for four hours & gravimetric samples were obtained at hourly intervals of exposure.

3

on preweighed Gelman DM-450 Metrical Membrane filters via stainless steel probe extended into the breathing zone of the Test animals. The test atmosphere were sampled at the rate of 10 L/minute for 3 minutes for Group 2 and 30 seconds to 1 minute for Group 3. Particle size distribution samples were obtained during the exposure using an Andersen Mini Sampler Cascade Impactor placed inside the chamber on top of the animal cage. The chamber atmosphere for particle sizing were sampled at a rate of 1.4 L/min for 5 minutes for group 2 and 3 minutes for group 3. Samples were obtained after 60 and 180 minutes of exposure. Percentages of total dry weight gain on the collection plates and backup filters were cumulatively plotted against cutoffs on Log-normal paper and from this the mass median aerodynamic diameters (MMAD) and geometric Standard deviations extrapolated.

	Group I	Group II	Group III
	Control	Test	Test
Nominal Concentration	—	14.52 mg/L	21.70 mg/L
Mean Gravimetric Concentration	—	2.98 mg/L	3.54 mg/L
Mass Median aerodynamic diameter	—	3.4 ± .29 (Maximum attainable level)	2.8 ± 0.14

All animals were observed prior, during and for the post exposure periods. During exposure the observations were at 30 minute intervals and Twice daily during the 14 day post exposure

period. Necropsy was performed at termination and at death. Mortality was within 24 hrs in both test groups. Necropsy of these animals revealed that the lungs had failed to collapse in one and the other had dark red lungs.

All animals were covered with dust at exposure. Signs of systemic toxicity during exposure included lanquid appearance & dyspnea in group II and lanquid appearance, chin rubbing and bloody crust on nose in group III. All these symptoms disappeared by day 2 and the animals remained normal to day 14.

At Necropsy the only gross observations were pinpoint red areas on the lungs of 1 control animal, dilated pelvis of kidneys of one control and two group II animals, and vaccine horns filled with fluid in 3 animals, two in group II and one in group III.